IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MERIX PHARMACEUTICAL CORPORATION ,	)	
v.	)	**No. 5 C 1403**
GLAXOSMITHKLINE CONSUMER HEALTHCARE, L.P., AND SMITHKLINE BEECHAM COPORATION.	)	**Wayne R. Andersen District Judge**

MEMORANDUM, OPINION AND ORDER

In February 2005, GlaxoSmithKline Consumer Healthcare, L.P. ("GSK") filed suit in New Jersey federal court against Merix Pharmaceutical Corp. ("Merix") challenging the advertising of ViraMedx RELEEV, an over-the-counter ("OTC") cold sore drug manufactured and marketed by Merix. Approximately one month later, Merix filed suit in this Court against GSK, challenging the advertising for Abreva, an OTC cold sore drug marketed by GSK, and Valtrex, a prescription medication used to treat cold sores, genital herpes, and shingles, both of which compete with RELEEV. Merix claims GSK's advertising of Abreva and Valtrex violates (i) the Illinois Consumer Fraud and Deceptive Business Practice Act, 815 ILCS 505/1, *et seq.* (the "ICFA"); (ii) the Illinois Uniform Deceptive Trade Practices Act, 815 ILCS 510/1, *et seq.* (the "IDTPA"); (iii) the federal Lanham Act; and (iv) Illinois common law. With respect to Valtrex, Merix contends that GSK's statements that the drug is a "One-Day Cold-Sore Treatment" for cold sores and "3-Day Outbreak Therapy" for genital herpes on the internet, in print, press releases and television advertising are false and misleading and therefore in violation of the ICFA, IDTPA, Lanham Act and Illinois common

law. The advertising is alleged to have occurred within the Northern District of Illinois.

The Food and Drug Administration ("FDA") approved Valtrex in 1995 pursuant to a New Drug Application. The FDA directed that "patients should be instructed that treatment for cold sores should not exceed 1 day (2 doses)." With respect to genital herpes, the FDA approved a recommended dosage of "500 mg twice daily for 3 days" for the treatment of recurrent episodes and "1 gram twice daily for 10 days" for the treatment of initial episodes.

Merix characterizes GSK's statements that Valtrex is a "One-Day Cold-Sore Treatment" for cold sores and "3-Day Outbreak Therapy" for genital herpes as a "campaign of deception regarding the efficacy of its drugs and unscientific conclusions based on unreliable test data." GSK contends its advertising does no more than repeat what the FDA requires it to inform patients who take, and doctors who prescribe, Valtrex. Merix points to studies evidencing that GSK's "One-Day Cold Sore Treatment" and "3-Day Outbreak Therapy" are false and misleading statements and thus violate the ICFA, IDTPA, Lanham Act and Illinois common law. It claims the statements "influence purchasing decisions and mislead unwitting doctors into recommending and prescribing" the drug. Merix claims these practices divert sales away from Merix to GSK and, as a result, it is entitled to an injunction, damages, an accounting of GSK's profits on Valtrex sales, and attorneys' fees.

Standard of Review

A motion for judgment on the pleadings pursuant to Rule 12(c) is reviewed under the same standard that applies to dismissals under Rule 12(b)(6) for failure to state a claim upon which relief can be granted. *See R.J. Corman Derailment Servs., L.L.C. v. Int'l Union, Local Union 150*, 335 F.3d 643, 647 (7th Cir. 2003). A motion for judgment on the pleadings should be granted "only if it appears beyond doubt that the plaintiff cannot prove any facts that would support his claim for

relief." *Thomas v. Guardsmark, Inc.*, 371 F.3d 701, 704 (7th Cir. 2004). This Court must accept all well-pleaded allegations as true, drawing all reasonable inferences from those facts in the Plaintiff's favor. *Id.*

Rule 9(b)

Each of Plaintiff's claims, though framed under distinct legal theories, all emanate from the same factual allegations – that the Defendant committed consumer fraud by disseminating false and misleading advertising. Claims alleging consumer fraud under the ICFA and Lanham Act must be plead with particularity under Fed. R. Civ. P. 9(b). *See B. Sanfield, Inc. v. Finlay Fine Jewelry Corp.*, 857 F.Supp. 1241, 1243-44 (N.D. Ill. 1994) To meet this heightened standard, a plaintiff alleging fraudulent misconduct must state "the identity of the person making the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated." *Bankers Trust Co. v. Old Republic Ins. Co.*, 959 F.2d 677, 683 (7th Cir. 1992). When the alleged fraud occurred over a period of time, the Rule's pleading requirements – including the "time" requirement – apply less stringently. *Mutuelle Generale Francaise Vie v. Life Insurance Co. of Pennsylvania*, 688 F. Supp. 386, 393 (N.D. Ill. 1988). The plaintiff does not have to allege evidentiary details, rather, it is only required to "set forth the basic outline of the scheme, who made what representations and the general time and place of such misrepresentations." *Mutuelle Generale Francaise Vie*, 688 F. Supp. At 393. In fact, the "identity" requirement is met when a plaintiff pleads only the entity making the statement, the place requirement is satisfied by a general statement setting forth that the statements were made in all fifty states, the content requirement only mandates that the plaintiff mention the type and nature of the misleading statements, and the "method" requirement is reached by pleading the type of advertising in which the statements appeared. *Hot*

Wax, Inc. V. Grace-Lee Products, Inc., No. 97 C 6882 (N.D. Ill. Sept. 15, 1998), 1998 WL 664945.

Based on these considerations, this Court finds that Merix has met the Rule 9(b) particularity requirements. First, Merix identifies the entity making the alleged misrepresentations – Defendant GSK – thereby satisfying the "identity" requirement. Second, Merix satisfies the "time" requirement by asserting that GSK is making the alleged misrepresentations on an ongoing basis. Third, Merix asserts GSK committed the alleged fraudulent activity in the Northern District of Illinois and therefore satisfies the "place" requirement. Fourth, the complaint fulfills the "content" requirement by identifying the "One-Day Cold-Sore Treatment" and "3-Day Outbreak Therapy" statements about Valtrex as the false and misleading advertising claims. Fifth, the complaint alleges that GSK marketed its products through "the internet, in print, press releases, point-of-purchase and television advertising," thereby satisfying the method requirement. For the reasons above, this Court denies GSK's motion with respect to Rule 9(b) pleading requirements.

ICFA Claims

The ICFA prohibits unfair methods of competition, including the use of false or misleading information in the conduct of commerce with intent that others rely upon the information. *815 Ill. Comp. Stat. 505/2*. To establish a violation of the ICFA's prohibition on deceptive acts or practices, a plaintiff must prove that: (1) the defendant engaged in a deceptive act or practice; (2) the defendant intended that the plaintiff rely on the act or practice; and (3) the act or practice occurred in the course of conduct involving trade or commerce. *Zekman v. Direct Am. Marketers, Inc.*, 182 Ill. 2d 359, 695 N.E.2d 853, 860, 231 Ill. Dec. 80 (Ill. 1998); *Siegel v. Levy Org. Dev. Co.*, 153 Ill. 2d 534, 607 N.E.2d 194, 198, 180 Ill. Dec. 300 (Ill. 1992). If the alleged deceptive practice implicates consumer protection concerns, a defendant's competitor may bring an ICFA claim. *B. Sanfield, Inc. v. Finlay*

Fine Jewelry Corp., 857 F. Supp. 1241 (N.D. Ill. 1994). Under the ICFA, a statement is deceptive if it creates a likelihood of deception or has the capacity to deceive. *People ex rel. Hartigan v. Knecht Servs., Inc.*, 216 Ill. App. 3d 843, 575 N.E.2d 1378, 1387, 159 Ill. Dec. 318 (Ill. App. Ct. 1991); see also *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 938 (7th Cir. 2001). When determining whether a statement has the capacity to deceive, courts should examine the statement in the context of other information available to consumers. *See Bober*, 246 F.3d at 940.

GSK seeks dismissal under an ICFA section explicitly setting forth that no conduct specifically authorized by any regulatory body of Illinois or the United States of America can create liability under the statute. 815 ILCS 505/10b(1). The Seventh Circuit has explained that this section ensures that the ICFA "will not impose higher disclosure requirements on parties than those that are sufficient to satisfy federal regulations." *Bober v. Glaxo Wellcome PLC*, 246 F.3d 934, 941 (7th Cir. 2001). At the same time, the "exemption is not available for statements that manage to be in technical compliance with federal regulations, but which are so misleading or deceptive in context that federal law itself might not regard them as adequate." *Id.*

Many of Merix's allegations concerning Valtrex are lifted from the Prescribing and Patient Information. Merix argues that the dosage recommendations, clinical study data and notifications made in the information sheets prove that GSK is disseminating broad, baseless statements to "unwitting consumers and health care professionals." The Prescribing and Patient Information, however, are also the genesis for the statements GSK made in its advertising campaign for Valtrex.

Judge Zagel noted in a nearly identical context concerning a class action pending against GSK, "there is not enough information in the complaint to state definitively that GSK's statements are labeling that is specifically authorized by the FDA... It may [] be possible for GSX to show that the

marketing was almost identical to the specifically authorized labeling, but at this point, there is no evidence to decide one way or the other" *Annette Scott v. Glaxosmithkline Consumer Healthcare, L.P.*, No. 05 C 3005 (N.D. Ill. April 12, 2006). We agree that, at this point, there is insufficient information for us to determine whether the Valtrex advertising campaign falls under the purview of the ICFA exemption for statements authorized by the FDA. Accordingly, GSK's motion is denied as to the ICFA claims.

Lanham Act & Common Law Claims

GSK asks us to dismiss the Lanham Act claims because "there is no private right of action under the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. §§ 321, *et seq.*, [("FDA Act")] and therefore a private party has no standing to challenge whether a competitor has properly obtained FDA approval, or to look behind the FDA's approval and question whether the FDA acted properly." However, Merix's Complaint does not seek to assert a private right of action under the FDA Act. Instead, Merix argues that GSK's statements are literally false, and hence actionable under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). Courts routinely allow this type of claim to go forward, regardless of whether or the allegedly false statements are within the purview of the FDA. *Grove Fresh Distributors, Inc. v. Flavor Fresh Foods, Inc.*, 720 F.Supp. 714, 716 (N.D.Ill. 1989) ("The fact that [plaintiff] refers to or relies on an FDA regulation defining orange juice to support its Lanham Act claim is not grounds for dismissal.)

GSK also asks us to dismiss the IDTPA claim because that statute is "merely a codification of the Illinois common law of unfair competition." However, we have allowed the ICFA claim to proceed. Merix pleaded a claim that falls within the IDTPA and the Illinois common law of unfair competition.

Conclusion

For the above stated reasons, Merix's motion to dismiss the Valtrex claims [38] is denied.

It is so ordered.

Wayne R. Andersen
United States District Court

Dated: June 28, 2006